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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,264	11/26/2003	Rasmus B. Jensen	02716.0005.NPUS01	4282
27194	7590	09/27/2007	EXAMINER	
HOWREY LLP			MONSHIPOURI, MARYAM	
C/O IP DOCKETING DEPARTMENT			ART UNIT	PAPER NUMBER
2941 FAIRVIEW PARK DRIVE, SUITE 200			1656	
FALLS CHURCH, VA 22042-2924				
MAIL DATE		DELIVERY MODE		
09/27/2007		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/724,264	JENSEN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Maryam Monshipouri	1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,4-9, 13-19, 21 and 22 is/are pending in the application.
  - 4a) Of the above claim(s) 13, 15-19, 21 and 22 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1,4, 5, 7-9 and 14 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)               |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application     |
| Paper No(s)/Mail Date <u>11/06, 1/06&amp; 10/04</u> .                                  | 6) <input checked="" type="checkbox"/> Other: <u>see attachment</u> . |

Applicant's response to restriction requirement filed 7/27/2007 is acknowledged.

Applicant elected Group I (claims 1, 4-5, 7-9, 14, SEQ ID NO:3 , SEQ ID NO:165) with traverse. Claims 13, 15-22 and all other recited sequences in claims are withdrawn as drawn to non-elected invention.

In traversal of restriction requirement applicant argues the following: (1) applicant has amended the claims such that instant claim 1 is a linking claim and has a technical feature of comprising a mutation in a conserved histidine residue of a wild type proteorhodopsin variant, which distinguishes from any prior art and naturally occurring proteorhodopsin variants are highly conserved. The technical feature of a conserved histidine is patentable and is applicable to any naturally occurring proteorhodopsin variant and is not limited to one or two variants. Therefore, applicant requests that the restriction requirement within Group I be subjected to the non-allowance of claim 1.

(2) SEQ ID NO:1-161 are naturally occurring proteorhodopsin variants. They are closely related and are highly conserved. Unless the examiner finds prior art against the linking claim it is unreasonable to force applicants to elect one variant over another as the concept is the same. Therefore the examiner is requested to examine all said sequences together.

(3) SEQ ID NO:164-178 should also be examined together because they are few in number and are closely related. Specially SEQ ID NO:163, 165, 167 only differ by one amino acid mutation site and therefore all said sequences should be examined together.

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(4) applicant has identified conserved amino acids (the special technical feature) that are involved in the relaying of protons through all-trans-retinal binding site but are not in direct contact with all-trans-retinal cofactor, which are likely to affect the pH dependent spectral shift and the pK<sub>rh</sub> value of proteorhodopsin and described method of their preparation and since they are shared by numerous proteorhodopsin variants no restriction should be imposed among the amino acid sequences of said variants.

These arguments were fully conserved but were found **unpersuasive**. With respect to applicant's **first** argument it should be reminded that instant claim 1 is unclear in term of what a mutant of a wild-type proteorhodopsin variant is. Applicant has only defined "proteorhodopsin variants" (see page 9 of the specification) as encompassing naturally occurring proteorhodopsin and their homologs. In page 10 the term "proteorhodopsin mutant" is defined as proteorhodopsin variant comprising one or more mutations. Therefore, in claim 1 it is unclear as to what the structure of a mutant of a homolog of proteorhodopsin is and where are said one or more conserved histidine residues to be substituted in all said variants. In view of the breadth of instant claims and their vagueness, the examiner would like to cite (US2007/0192889, published 8/2007, specifically SEQ ID NO:18926 (see the attached sequence alignment) which can be considered to be a homolog of proteorhodopsin of this invention having a "conserved histidine" substitution (see Histidine 193 of SEQ ID NO:18926) and would inherently have lower pK<sub>rh</sub> relative to the wild type "proteorhodopsin variant" of this invention as prior art against instant claim 1. Therefore, the special technical feature of this invention has been taught in the prior art and restriction remains.

With respect to applicant's **second and third** arguments, firstly the prior art is cited against instant claim 1, which brakes the unity of invention and secondly, even if there was no prior art against instant claim 1, applicant is well aware that in a single application only up to 10 sequences may be searched. Examining more than 10 sequences in a single application would require numerous hours (at least 200 hours) of searching which imposes and undue burden of searching on the Office and the examiner.

In response to applicant's **fourth** argument, the examiner fully appreciates applicant's invention, namely the identification of conserved residues in wild type proteorhodopsin, whose substitutions would lead to products with novel optical properties but she maintains that instant base claim 1 is not reciting applicant's invention but rather an invention that its unity of invention is broken (see above cited art) due to breadth of the claim. Furthermore, applicant is reminded that similarity among sequence structures does not necessarily justify withdrawal of restriction because in many instances products of highly similar structures have entirely different functions and are patentably distinct.

In conclusion, in view of response provided above, in addition to reasons provided previously, restriction remains and is hereby made **Final**.

#### DETAILED ACTION

Claims 1, 4-5, 7-9, 14 (SEQ ID NO:3 (Bac31A8), and SEQ ID NO:165 only) are under examination on the merits. Claims 2-3, 6, 10-12, 20 are canceled. Claims 13, 15-22 are withdrawn.

***Claim Objections***

Claims 4, 5, and 14 are objected to because of the following informalities: said claims still recite non-elected subject matter. Applicant is advised to delete non-elected subject matter from said claims. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-5, 7-9, 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "conserved histidine residue" in claim 1 (and its dependent claims 4-5, 7-8, 14) is unclear. Applicant has not defined said phrase specifically in the specification. In page 3, applicant provides some examples of such conserved histidine residues without specifically defining the metes and bounds of said phrase. Appropriate clarification is required.

Claims 1, 4-5, 7-9, 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "wild type proteorhodopsin variants" in claim 1 (and its dependent claims 4-5, 7-9, 14) is vague. Firstly, said phrase has not been specifically defined the specification. Secondly, if one assumes that said phrase is the same as "proteorhodopsin variants" (see page 9 of the specification), such variants are defined to encompass naturally occurring proteorhodopsin and their

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homologs. It is unclear what "naturally occurring variants" are and how much sequence (structural) identity qualifies an amino acid sequence as a homolog of "wild type or naturally occurring proteorhodopsin". In addition, it is totally unclear as to what a mutant of a homolog of a wild type proteorhodopsin is (see above wherein a response to traversal arguments is provided). Appropriate clarification is required.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is vague as to what a 90% homolog of a mutant of variant of wild type proteorhodoposin is. Also what is the difference between wild type proteorhodopsin and naturally occurring proteorhodopsin. Appropriate clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 7-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 (and its dependent claims 5, 7-9) are directed to genus of mutants which have been inadequately described in the specification.

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The court of Appeals for the Federal Circuit has recently held that such a general definition does not meet the requirements of 35 U.S.C. 112, first paragraph. "A written description of an invention involving chemical genus, like a description of a chemical species, requires a precise definition, such as be structure, formula {or} chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at \*23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). The court held that "in claims involving chemical materials, generic formulae usually indicate with specificity what generic claims encompass. One skilled in the art can distinguish such a formula fro others and can identify many of the species that the claims encompass. accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish it from others. One skilled in the art therefore cannot, as one can do with a fully described genus visualize the identity of the members of the genus". Here, applicant is claiming a genus of products by what they do rather than what they are and this kind of definition fails to meet the written description requirements of 112 first paragraph. It is true that some species such as sequences provided in claim 4 are provided but the breadth of claim 1 is such that such number of species fails to define all the members of the genus as broadly claimed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by La Rosa et al. (US2007/0192889 cited above). La Rosa teaches a sequence that has 22.4% similarity with SEQ ID NO:3 of this invention and can be considered to be a mutant of a variant of wild type proteorhodopsin variant (see its SEQ ID NO :18296 in the attached alignment ) wherein a histidine at position 193 is substituted with phenylalanine and wherein said mutant has lower pK<sub>rh</sub> relative to wild type proteorhodopsin variant, by inherency, anticipating claim 1.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m to 5:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*M. Monshi*  
Maryam Monshipouri Ph.D.

Primary Examiner

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